

REMARKS**A. Status of the Claims**

Prior to the submission of this paper, claims 44-85 were pending and under examination. In this paper, Applicants have requested the cancellation of claims 69 and 77 without prejudice or disclaimer. When these claim cancellations have been entered, the claims present for examination will be claims 44-68, 70-76, and 78-85.

Claims 44-69, 71, 76-77, 79, and 84-85 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent Application Publication No. 2002/0009491 to Rothbard et al. ("Rothbard").

Claims 70 and 78 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rothbard, in view of U.S. Patent No. 4,725,609 to Kull, Jr ("Kull").

Claims 72 and 80 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rothbard, in view of U.S. Patent No. 5,785,978 to Porter et al., ("Porter").

Claims 73 and 81 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rothbard, in view of U.S. Patent No. 5,902,593 to Kent et al. ("Kent").

Claims 74 and 82 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rothbard, in view of U.S. Patent No. 5,637,316 to Ribier ("Ribier").

Claims 75 and 83 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rothbard, in view of U.S. Patent No. 4,933,172 to Clark, Jr. ("Clark").

B. Explanation of the Amendments

In this paper, independent claims 44, 56, 68, and 76 have been amended to clarify the invention. Claims 44 and 56 have been amended so that their preambles now recite "A

cosmetic formulation comprising....”. Support for these amendments is generally found throughout the specification [e.g., see ¶[0011] of US Pre-grant Publication No. 2005/0226821(hereafter “Waugh ‘821”). Additionally, claims 68 and 76 have been rewritten.

Claim 68 now reads as follows:

68. A method for dilating blood vessels in a region of the body to achieve a cosmetic effect, said method comprising topically applying a dilating effective amount of a composition comprising a polymer having from 7 to 15 subunits, each subunit consisting of a member of the group selected from L-arginine and physiologically acceptable salts of L-arginine, to the region of the body to achieve the cosmetic effect.

Support for the amendments to claim 68 is found throughout Applicants’ specification. For example, ¶¶ [0008] and [0019] of Waugh ‘821 provides support for “topically applying a dilating effective amount of a composition.” Support for the phrase “polymer having from 7 to 15 subunits, each subunit consisting of a member of the group selected from L-arginine and physiologically acceptable salts of L-arginine,” is found in original claim 1 and 14. Support for the phrase “to achieve a cosmetic effect” is found in ¶[0007] of Waugh ‘821. A similar analysis applies for claim 76.

Dependent claims 45-55 and 57-67 have been amended to correct minor grammatical errors and to ensure that the preambles of these claims are consistent with the preambles of the corresponding independent claims.

Dependent claims 70 and 78 have been amended to specify that the “cosmetic effect is selected from the group consisting of prevention of hair loss, promotion of hair regrowth, increase in length or thickness of eyelashes, and increase in length or thickness of eyebrows”. Support for this amendment is found, for example, at ¶[0017] of Waugh ‘821.

Dependent claims 71 and 79 have been amended so that their preambles are consistent with the corresponding independent claims. Additionally, claims 84 and 85 have been

amended to depend from claims 71 and 79. Support for the amendments to claims 84 and 85 are found, for example, in ¶ [0038] of Waugh ‘821.

Dependent claims 72 and 80 have been amended to specify that the “cosmetic effect is selected from the group consisting of increased lip plumpness, a change in lip color, and a change in lip contour.” Support for this phrase is found at ¶ [0017] of Waugh ‘821.

Dependent claims 74, 75, 82 and 83 have been so that their preambles are consistent with the corresponding independent claims.

Applicants respectfully submit that no new matter has been added by these amendments.

C. Applicants’ Claims Are Patentable Over the Cited References

1. Rothbard Does Not Teach or Suggest the Claimed “Cosmetic Formulation”

Applicants’ independent claims 44 and 56, which are composition claims, have been amended such that their preambles specify that the claimed compositions are cosmetic formulations. For the reasons set forth below, Rothbard does not teach or suggest the compositions claimed in claims 44 and 56 or their corresponding dependent claims. Accordingly, the rejection of claims 44-67 under 35 U.S.C. § 103(a) should be withdrawn.

It is well established that “if the preamble is ‘necessary to give life, meaning, and vitality’ to the claim, then the claim preamble should be construed as if in the balance of the claim.” *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). For example, the Federal Circuit has held that a claim preamble reciting “an abrasive article” was essential to define the invention, because the composition claims merely recited an article comprising abrasive grains and a hardened binder. *Kropa v.*

Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). As the Federal Circuit noted in *Kropa*, “it is only by that phase [i.e., “an abrasive article”] that it can be known that the subject matter defined by the claims is comprised as an abrasive article. Every union of substances capable, *inter alia*, of use as abrasive grains and a binder is not an ‘abrasive article’”. *Id.* Thus, the preamble served to further define the structure of the article produced and gave meaning to the claim. See MPEP § 2111.02.

Here, the preambles of amended claims 44 and 56 help define the elements of the claimed compositions, just as the preamble in *Kropa* helped define the structure of the claimed article. For example, the elements of a “cosmetic formulation” containing L-arginine oligomers, as recited in Applicants’ claims, would not include anti-cancer compounds or imaging agents, even though Rothbard contemplates delivering such substances using L-arginine as a transport molecule. Indeed, one of ordinary skill in the art would not expect a “cosmetic formulation” to contain boron reagents for neutron capture therapy, anti-cancer compounds such as taxol, L-DOPA, cytotoxic metals, or gadolinium-doped chelating agents for magnetic resonance imaging (MRI), as recited in Rothbard. Thus, in direct analogy to *Kropa*, which held that not every union of substances capable of use as abrasive grains and a binder is an “abrasive article”, not every composition which contains L-arginine oligomers is a “cosmetic formulation”. Thus, the phrase “a cosmetic formulation” further defines and gives meaning to the claimed compositions.

The phrase “a cosmetic formulation” should be considered as a claim limitation of Applicants’ amended claims 44 and 56 for yet another reason. As the Federal Circuit noted, “clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention.” *Catalina Mktg. Int'l v. Coolsavings.com*,

Inc., 289 F.3d at 808-09, 62 USPQ2d at 1785. Here, Applicants claimed invention is distinguished from Rothbard, because nowhere does Rothbard teach that its compositions can be used as cosmetic formulations. At best, Rothbard merely states generically that its compositions include “any composition that can be used to the benefit of a mammalian species” [Rothbard, ¶ [0026]]. However, this broad statement, in and of itself, would not suggest to one of ordinary skill in the art that Rothbard’s compositions would be suitable for cosmetic formulations, given the countless possible benefits embraced by this broad language, as well as Rothbard’s teaching that its compositions apply to non-human mammals as well. Indeed, the Federal Circuit has held that when the claimed invention is a “needle-in-a-haystack” with respect to the disclosure in an earlier reference, the claimed invention is not obvious. *See, e.g., In re Luvisi*, 52 C.C.P.A. 1063, 1068 [holding that the claimed borate compositions were a “needle-in-a haystack” in view of the cited reference, and therefore were not obvious].

Thus, Applicants conclude that Rothbard fails to teach or suggest any composition that can be fairly construed as a “cosmetic formulation”. For at least this reason, amended claims 44 and 56, as well as their corresponding dependent claims, are patentable over Rothbard. MPEP § 2143.03.

Applicants’ claims are not obvious over Rothbard for another reason. It is well established that omission of an element while retaining its function is an indication of non-obviousness. *In re Edge*, 359 F.2d 896, 149 USPQ 556 (CCPA 1966). As Applicants noted previously, Rothbard only describes compositions that have, at a minimum, two components: (1) a biologically active agent; and (2) a delivery-enhancing transport molecule, which can be arginine oligomers. Applicants, on the other hand, have recognized that arginine oligomers, without the presence of an additional biologically active agent, can have a beneficial effect, such

as a cosmetic effect. [see Waugh '821, ¶ [0012], and Examples 1 and 2, and Applicants' claims]. Nowhere is this taught or suggested in Rothbard. Moreover, the Examiner has not demonstrated that arginine oligomers were recognized in the art, at the time this invention was filed, to be useful for achieving a cosmetic effect. At best, the Examiner cites an article by Ignarro et al., (Circ. Res. 1989; 64; 315-329) (hereafter, "Ignarro") to show that the vasodilating properties of polyarginine polymers were well known in the art [Office Action, page 20]. However, Applicants do not contest that the vasodilating properties of polyarginine were known, and further point out that Applicants even describe the vasodilating properties of L-arginine in the first paragraph of their own specification. The more important point is that none of the cited references teach or disclose that L-arginine oligomers can produce a cosmetic effect or can be used in cosmetic formulations, as recited in Applicants' claims.

In view of the foregoing, Applicants respectfully request the reconsideration and withdrawal of the rejection of composition claims 44-67.

2. Rothbard Does Not Teach the Method of Amended Claims 68 and 76

Applicants traverse the rejection of claims independent claims 68 and 76 for being unpatentable over Rothbard. As discussed in detail below, Rothbard fails to teach or suggest all of the elements of Applicants' amended method claims 68 and 76. Accordingly, the rejection should be withdrawn. MPEP § 2143.03.

Amended claim 68 is illustrative and recites the following:

68. A method for dilating blood vessels in a region of the body to achieve a cosmetic effect, said method comprising topically applying a dilating effective amount of a composition comprising a polymer having from 7 to 15 subunits, each subunit consisting of a member of the group selected from L-arginine and physiologically acceptable salts of L-arginine, to the region of the body to achieve the cosmetic effect.

Rothbard, however, fails to teach or suggest the step of “topically applying a dilating effective amount of a composition...to achieve [a] cosmetic effect” as recited in claim 68. In fact, Rothbard is completely silent on compounds for vasodilation. Furthermore, as noted above, Rothbard is completely silent on the “cosmetic formulations” and does not discuss any method of achieving a “cosmetic effect”. Because Rothbard fails to teach or suggest all of the claim elements of claim 68 and its corresponding dependent claims, these claims are patentable over Rothbard. MPEP § 2143.03.

For similar reasons, independent claim 76 and corresponding dependent claims 77-83 and 85 are also patentable over Rothbard. In particular, Applicants note that claim 76, like claim 68, recites the step of “topically applying a dilating effective amount of a composition...to achieve [a] cosmetic effect”, which is not taught or suggested in Rothbard. Accordingly the rejection of these claims for being unpatentable over Rothbard should be withdrawn as well. MPEP § 2143.03.

3. Applicants' Claims Are Patentable Over Rothbard in Combination with the Cited Secondary References

The Examiner attempts to arrive at the subject matter covered in Applicants' dependent claims by combining Rothbard with a variety of secondary references (i.e., Kull, Porter, Kent, Ribier, and Clark). In each case, the Examiner combines Rothbard with a secondary reference that describes a substance to be used as a “biologically active agent” in Rothbard's non-covalent conjugate. For example, in the proposed combination of Rothbard with Kull, the biologically active agent for promoting angiogenesis is nicotinamide (see Kull, col. 1, lines 1-10 and Office Action, page 9, wherein it refers to Kull's description of the topical

delivery of an “agent”). Thus, in each of these combinations of Rothbard with a secondary reference, the resulting system is a two-component non-covalent conjugate.

In the previous response, Applicants noted that Applicants’ inventive compositions do not require an additional biologically active agent to achieve a beneficial effect. As Applicants explained, simply the fact that the Examiner must resort to a combination of agents to produce an a beneficial effect achieved by Applicants using arginine alone confirms the non-obviousness of Applicants’ claimed invention. This conclusion is supported by Federal Circuit case law, which makes it clear that omission of an element while retaining its function is an indication of non-obviousness. *In re Edge*, 359 F.2d 896, 149 USPQ 556 (CCPA 1966).

Moreover, Applicants note that even if one considers Rothbard in combination with various secondary references, as proposed by the Examiner, the resulting combinations do not teach or suggest all of the claim elements in Applicants’ amended claims. For example, the resulting combinations do not teach or suggest “topically applying a dilating effective amount of a composition... to achieve [a] cosmetic effect” as recited in Applicants claims. Accordingly, the rejection of claims 70, 72-75, 78, and 80-83 under 35 U.S.C. § 103(a) for being unpatentable over Rothbard, in view of these secondary references, should be withdrawn.

CONCLUSION

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims and allowance of this application.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 50-3732, Order No. 13720-105110US1.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 50-3732, Order No. 13720-105110US1.

Respectfully submitted,
KING & SPALDING, L.L.P.

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By: /Joseph D. Eng Jr./
Joseph D. Eng Jr. / Kenneth H. Sonnenfeld
Registration No. 54,084 / 33,285

Correspondence Address:

King & Spalding LLP
1185 Avenue of the Americas
(212) 827 - 4318 Telephone
(212) 556 - 2222 Facsimile